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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,695	04/19/2001	Naomi Balaban	3908P2538	1785

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,695	BALABAN, NAOMI	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/28/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on October 18, 2004 is acknowledged. Claims 2-4 and 6 have been cancelled. Claims 1and 5 are under consideration in this office action.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The benefit of the earlier filing date under 35 U.S.C. 120 of the parent application Serial No. 09/054,331 now US Patent 6,291,431 has been denied for claims 1 and 5 for the instant application. The claims in the instant continuation-in-part application recites a feature, i.e. an isolated RAP polypeptide having an amino acid sequence of SED ID NO:13 (claim 1) and a vaccine comprising the RAP polypeptide of claim 1 or an antigenic ally effective portion thereof, and a pharmaceutically acceptable carrier (claim 5) which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent application. This feature has been first introduced and adequately supported in the instant continuation-in-part application and thus such claims are entitled only to the filing date of the instant application; *In re Von Lagenhoven*, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972) and *Chromalloy American Corp. v. Alloy Surfaces Co., Inc* ., 339 F. Supp. 859, 874, 173 USPQ 295, 306 (D. Del. 1972).

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 1D is not labeled as such. Figure 5 refers to sequences without sequence identifying numbers being described within the figure itself or the brief description of the drawings within the specification. Therefore, appropriate correction is requested.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 1 and 5 are objected to because of the following informalities: Claim recites "SEQ ill NO:13" however it should recite "SEQ ID NO:13." Claim 5 recites " or an antigenic ally effective portion thereof, and a phannaceutically acceptable carrier" Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is drawn to "a vaccine comprising the RAP polypeptide of claim 1 or an antigenic ally effective portion thereof, and a phannaceutically acceptable carrier". The written description in this case fails to set forth a specific antigenically effective portion thereof, therefore the written description is not commensurate in scope with the claims drawn to an antigenically effective portion thereof. Neither the specification nor the claims teach how to define an antigenically effective portion thereof. Neither the claims nor the specification teach how to obtain antigenically effective portions thereof. There is no guidance as to what the portions are; or what portions can or cannot be used in the vaccine being claimed. The specification does not include structural example of an antigenically effective portion thereof. Thus, the resulting antigenically effective portions thereof could result in a complexes not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Thus, a skilled artisan cannot envision the detailed structure of an antigenically effective portion thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Therefore the full breadth of the claim fails to meet the written description provision of 35 USC 112, first paragraph.

6. Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 refers to the acronym RAP which must be spelled out when used for the first time in a chain of claims. Appropriate correction is required to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Balaban et al., (Science 1998). The claim is drawn to "a vaccine comprising the RAP polypeptide of claim 1 or an antigenic ally effective portion thereof, and a phannaceutically acceptable carrier". It is presumed that the claim is drawn to a vaccine comprising the RAP polypeptide of claim 1 or an antigenically effective portion thereof, and a pharmaceutically acceptable carrier.

Balaban et al., teach that the synthesis of virulence factors i*n Staphylococcus aureus* is controlled by protein called RAP (RNAIII Activating Protein) (page 438). The authors purified the RAP protein (page 438). To test whether immunization with Rap could inhibit a *S. aureus* infection mice were either vaccinated with purified RAP from an *agr*-null strain or with a RAP from a wild-type *S. aureus* strain. The sequence of the strain has been previously documented (page 438). The RAP protein comprises amino acids with the general formula IKKY(K or S)PXTN where C is C, W or I. The instant specification at page 12, teach this formula as an antigenically effective portion. The RAP with complete Freund's adjuvant was the first injection and the second and third injections were with RAP and incomplete Freund's adjuvant (page 440). The RAP vaccinated mice remained free of disease (page 438).

Therefore, Balaban et al., teach a vaccine comprising the RAP polypeptide of claim 1 or an antigenically effective portion thereof, and an adjuvant which is pharmaceutically acceptable carrier.

8. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Balaban et al., (WO 99/32133). It is presumed that the claim is drawn to a vaccine comprising the RAP polypeptide of claim 1 or an antigenically effective portion thereof, and a pharmaceutically acceptable carrier.

Balaban et al., teach methods and compositions for the treatment and prevention of *Staphylococcus aureus* infections. The art teaches virulence factors in *Staphylococcus aureus* which are controlled by protein called RAP (RNAIII Activating Protein) (page 1 lines 12-20). The authors' teach the purification of the RAP protein from wild type *S. aureus* and from a null strain in their Experimental Examples, see the section entitled *in vivo* studies of mice (page 11 lines 1-14). Then the inventors also teach immunization with RAP (page 11 lines 16). Mice were either vaccinated with purified RAP from an *agr*-null strain or with a RAP from a wild-type *S. aureus* strain (page 11 lines 18-21). The RAP protein comprises amino acids with the general formula IKKY(K or S)PXTN where C is C, W or I. The instant specification, at page 12, teach this formula as an antigenically effective portion. The RAP was injected with complete Freund's adjuvant on the first inject and with incomplete Freund's adjuvant on the second and third injections (page 11 lines 23-30).

Thus, Balaban et al., teach a vaccine comprising the RAP polypeptide of claim 1 or an antigenically effective portion thereof, and an adjuvant which is pharmaceutically acceptable carrier.

Prior Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Balaban et al., US Patent 6,291,431 teach methods and compositions for the treatment and prevention of staphylococcal infections. Balaban et al., (PNAS 1995) teach RAP as a vaccine against the expression of *agr*-induced virulence factors which could interfere with the ability of the bacteria to establish and maintain an infection. Korem et al., FEMS Microbiology Letters 223(2003) 167-175 teach characterization of RAP. Lee teach an experimental vaccine that targets staphylococcal virulence, specifically immunization with RAP.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
December 22, 2004

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